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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/017,393

12/18/2001

Karl F. Kovacs

16U 103 R1

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12/23/2004

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EXAMINER

MURPHY, JOSEPH F

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 12/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/017,393

Applicant(s)

KOVACS ET AL.

Examiner

Joseph F Murphy

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/22/2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 6-12, 17 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 2, 13-16 and 18 is/are allowed.
- 6) ☒ Claim(s) 3-5 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Formal Matters

Claims 1-19 are pending. Claims 6-12, 17 stand withdrawn from consideration pursuant to 37 CFR 1.142(b). Claims 15, 13-16, 18-19 are under consideration.

Response to Amendment

The rejection of claims 13-16 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter has been obviated by Applicant's amendment and is thus withdrawn.

The rejection of claims 2, 13-16 under 35 U.S.C. 112, first paragraph as lacking enablement has been obviated by Applicant's amendment and is thus withdrawn.

The rejection of claims 2, 13-16 under 35 U.S.C. 112, first paragraph as lacking written description has been obviated by Applicant's amendment and is thus withdrawn.

The rejection of claims 2-5, 13-16, 19 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been obviated by Applicant's amendment.

New and remaining issues are set forth below.

Claim Rejections - 35 USC § 112 first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-5, 19 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated human H2R polynucleotide comprising polynucleotide sequence having 95% or more sequence identity along the entire length of the polynucleotide sequence set forth in SEQ ID NO: 1 and which codes without interruption for H2R, or a complete complement thereto, wherein said polynucleotide hybridizes under high stringency conditions comprising 5X SSC. 0.5% SDS. 100 ug/ml denatured salmon sperm DNA and 50% formamide at 42C to the complete complement of the sequence set forth in SEQ ID NO: 1 and wherein said polynucleotides codes for a polypeptide that binds histamine, and also for an isolated H2R polynucleotide, comprising: a polynucleotide coding for amino acids 360-422 of SEQ ID NO 2, specific fragments thereof which hybridize specifically under high stringent conditions to the polynucleotide sequence from nucleotide positions 1 180-1368 as set forth in SEQ ID NO:1, or complete complements thereto, wherein said H2R polynucleotide encodes a polypeptide which binds histamine, does not reasonably provide enablement for an isolated H2R polynucleotide, comprising: a polynucleotide coding for amino acids 360-422 of SEQ ID NO 2, specific fragments thereof which hybridize specifically under high stringent conditions to the polynucleotide sequence from nucleotide positions 1 180-1368 as set forth in SEQ ID NO:1, or complete complements thereto, for reasons of record set forth in the Office Action of 07/27/2004. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The rejection of record set forth that the claims are drawn to polynucleotides that have varying sequences, because they are fragments. Thus, the claims are overly broad since

insufficient guidance is provided as to which of the myriad of variant polynucleotides encompassed will encode polypeptides which will retain the characteristics of human H2R. The claims as written do not set forth a function for the encompassed polynucleotides, or encoded polypeptides. Applicant is required to enable one of skill in the art to make and use the claimed invention, while the claims encompass variant polynucleotides and it would require undue experimentation for one of skill in the art to make and use the claimed polypeptides, since the skilled artisan would have to first make variant polynucleotides encoding polypeptides of SEQ ID NO: 2, then determine a function, then test for that function. Because the amino acid sequence of a polypeptide determines its structural and functional properties, and predictability of which amino acids can be substituted is extremely complex, accurate predictions of a polypeptide's structure from mere sequence data are limited. Thus, since Applicant has only taught how to test for variant polynucleotides encoding polypeptides of SEQ ID NO: 2, and has not taught how to make variant polynucleotides encoding polypeptides of SEQ ID NO: 2, it would require undue experimentation of one of skill in the art to make and use the claimed polynucleotides.

Claims 3-5, 19 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for reasons of record set forth in the Office Action of 07/27/2004. Applicant is directed to the Guidelines for the Examination of Patent Applications

Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

The rejection of record set forth that these are genus claims because the claims are drawn to polynucleotides that are fragments. The instant claims do not set forth a functional limitation for the encoded polypeptide. The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between structure and function structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. In the instant case, the specification fails to provide a correlation between structure and function, since no clear function is set forth for the claimed polynucleotides or encoded polypeptides. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Applicant argues that the Written Description Guidelines provides examples of a claim that covers sequences that hybridize to a recited sequences, which encodes proteins with a particular function. However, in the instant case, the claims as written do not set forth a function for the encoded polypeptides, and thus the written description requirement has not been satisfied.

Claim Rejections - 35 USC § 112 second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-5, 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is vague and indefinite in the recitation of the term "specific fragments". The term "specific" seems to indicate that there is a list of fragments that are encompassed, or some other way to determine whether a fragment is "specific", but the claim does not set forth the method by which a fragment is to be determined to be specific. Thus, the metes and bounds of the claim cannot be determined. Claims 4-5, 19 are rejected insofar as they depend on the recitation in claim 3 of "specific fragments".

Claim 3 recites the term "high stringent conditions", which is a conditional term and renders the claim indefinite. Furthermore, some nucleic acids which might hybridize under conditions of moderate stringency, for example, would fail to hybridize under conditions of high stringency. The metes and bounds of the claim thus cannot be ascertained. This rejection could be obviated by supplying specific conditions supported by the specification which Applicant considers to be highly stringent. Claims 4-5, 19 are rejected insofar as they depend on the recitation in claim 3 of "high stringent conditions".

Conclusion

Claims 1-2, 13-16, 18 are allowable.

Claims 3-5, 19 are rejected.

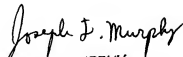
Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Murphy whose telephone number is (571) 272-0877. The examiner can normally be reached Monday through Friday from 7:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joseph F. Murphy, Ph. D.
Patent Examiner
Art Unit 1646
December 21, 2004


JOSEPH MURPHY
PATENT EXAMINER